K123120

DEC 1 2 2012

4.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

4.1 SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

a. Applicant:
Alcon LenSx, Inc.
33 Journey
Aliso Viejo, CA 92656
Tel: (949) 360-6010
Fax: (949) 360-6028

b. Contact Person:
Judy Gordon, D.V.M.
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651
judy@clinregconsulting.com
Tel: (949) 715-0609
Fax: (949) 715-0610

4.2 NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LenSx Laser System

b. Common/Usual Name: LenSx Laser System

c. Classification Name: Laser Instrument, Surgical, Powered

d. Classification Code(s): 21 CFR 886.4390; OOE, HQC, HNO

4.3 PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
Laser System		
K120732	LenSx Laser System	Alcon LenSx, Inc.
Patient Interface Accessory		
K100244	Metro Soft, Hydrogel Soft Contact Lens	Metro Optics of Austin, Inc.

4.4 DEVICE DESCRIPTION

The LenSx Laser System uses focused femtosecond laser pulses to create incisions and separate tissue in the lens capsule, crystalline lens, and the cornea. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce a continuous incision or tissue separation.

The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision. The laser pulses are delivered through a Patient Interface accessory that is placed on the surface of the cornea and fixes the eye with respect to the delivery system.

This 510(k) premarket notification is being submitted to seek clearance for an additional patient interface accessory to be offered for use with cataract procedures in addition to the original patient interface accessory to the LenSx Laser System (cleared under K120732 for cataract and lamellar resection procedures). The SoftFit Patient Interface differs from the original Patient Interface (K120732) in that it has an extended suction ring skirt that enables positioning of a soft contact lens against the internal surface of the patient interface glass. The soft contact lens is similar to a standard daily wear contact lens indicated for the correction of ammetropia, with a slightly modified edge to enable fitting into the SoftFit Patient Interface. The materials and manufacturing processes used for the soft contact lens component of the proposed SoftFit Patient Interface accessory are identical to the processes used for the predicate daily wear soft contact lens (K100244).

With the soft contact lens insert in place, the SoftFit Patient Interface is then mounted onto the LenSx laser system for docking onto the eye in a manner that is identical to the original LenSx Laser Patient Interface. As a result, use of the soft contact lens substantially reduces intraocular pressure (IOP) during the laser procedure, enhancing comfort and addressing potential concerns in patients with a history of glaucoma.

For cataract procedures, either a LenSx Laser Patient Interface or a SoftFit Patient Interface may be used. The original LenSx Laser Patient Interface is used for keratoplasty and corneal flaps.

4.5 INDICATION FOR USE

The following indications for use for the LenSx Laser System are unchanged from the previously cleared device (K120732):

- In the creation of corneal cuts/incisions, anterior capsulotomy and laser phacofragmentation during cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.
- In the creation of a lamellar cut/resection for lamellar keratoplasty, and in the creation of a penetrating cut/incision for penetrating keratoplasty
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea

4.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx Laser is unchanged and this 510(k) is intended to introduce an alternative Patient Interface accessory (the SoftFit Patient Interface) for use with cataract surgery procedures. The original Patient Interface (cleared under K120732) will continue to be available for use with cataract, keratoplasty and corneal flap procedures.

The SoftFit Patient Interface consists of a slightly modified Patient Interface and a daily wear soft contact lens insert. The SoftFit PI has an extended suction ring skirt that enables positioning of the contact lens against the internal surface of the patient interface glass. The soft contact lens is identical to standard daily wear contact lens indicated for the correction of ammetropia (K100244), with a slightly modified edge to enable fitting into the SoftFit Patient Interface. The outer curvature of the soft contact lens matches the internal curvature of the patient interface glass. The inner curvature of the soft contact lens approximates the average corneal curvature. With the soft contact lens in place, the SoftFit Patient Interface is then mounted onto the LenSx Laser system for docking onto the eye in a manner that is identical to the original Patient Interface. The SoftFit Patient Interface results in a significantly lower intraocular pressure elevation during the laser procedure than the original Patient Interface.

4.7 BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the SoftFit Patient Interface accessory include:

- Evaluation of the holding force and average intraocular pressure increase generated by original and SoftFit Patient Interfaces.
- Evaluation of the accuracy and reproducibility of the depths and geometry of each of the previously cleared cataract treatment patterns for the LenSx Laser when the SoftFit Patient Interface is used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 12, 2012

Alcon LenSx, Inc.
% Ms. Judy F. Gordon, D.V.M.
Regulatory Consultant to Alcon LenSx, Inc
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K123120
Trade/Device Name: LenSx® Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: OOE, HQC, HNO
Dated: November 26, 2012
Received: November 27, 2012

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K123120

Device Name(s): LenSx® Laser System

Indications for Use:

The LenSx Laser System is indicated for use:

- In the creation of corneal cuts/incisions, anterior capsulotomy and laser phacofragmentation during cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.
- In the creation of a lamellar cut/resection for lamellar keratoplasty, and in the creation of a penetrating cut/incision for penetrating keratoplasty.
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

David P Todd

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K123120